July 23, 1998

Dear Colleague:

The Center for Biologics Evaluation and Research (CBER) is sponsoring two open public meetings to solicit views and comments on how the Food and Drug Administration (FDA) can best meet its statutory obligations under the Food, Drug and Cosmetic Act as amended by the FDA Modernization Act (FDAMA) of 1997. These two public meetings have identical content and are scheduled as follows:

Date and Time: August 14, 1998, 9:00am to 5:00pm
Location: Department of Health and Human Services
Hubert H. Humphrey Building
Penthouse Conference Room (Room 800)
200 Independence Avenue, S.W.
Washington, D.C. 20201

Date and Time: August 28, 1998, 9:00am to 5:00pm
Location: Oakland Federal Building
Royball Auditorium
1301 Clay Street (between 12th and 14th Streets)
Oakland, CA 94612

Section 406(b) of the FDAMA requires the Agency to consult with its external stakeholders, specifically "appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry." Following these consultations, FDA will publish a plan for achieving compliance with each of its obligations under the Food, Drug and Cosmetic Act. The FDAMA has identified six objectives that will be addressed in the Agency plan. These objectives are outlined in the attached Federal Register notice.

FDA welcomes the opportunity to hear your comments, views and proposals on how to accomplish these 406(b) objectives. As you know, CBER has undertaken a number of important initiatives to streamline regulatory procedures, establish new priorities and implement managerial reforms. Despite this progress, the Agency and CBER face the increasingly difficult task of meeting all of its mandates and statutory requirements.

FDA is requesting your comments on how it can best meet its statutory obligations within the context of the six objectives described in FDAMA. The Agency is requesting that you address the following questions at the public meetings:

1. From your vantage point, are there objectives or issues related to the Agency's statutory obligations other than the six objectives identified in FDAMA that should be included in the FDA plan?
2. What do you believe FDA should do to adequately meet the demands that are beginning to pressure the application review process, especially for non-user fee products, so that it can meets its statutory obligations to achieve timely product reviews so that patients benefit from available and affordable treatments?
3. How can FDA work with its partners to ensure that products produced and marketed by regulated industry are of high quality and provide necessary consumer protection?
4. How can FDA best establish and sustain an effective, timely and science-based postmarketing surveillance system for reporting, monitoring, evaluating and maximizing its communications to health professionals and consumers about injuries associated with all FDA-regulated products?

5. What approach should FDA use to ensure that it has continued access to the scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process?
6. How can FDA best maximize its outreach efforts to ensure the availability and clarity of information about new products for consumers and patients, and about the process for the review of applications and submissions (petitions, notifications and other similar forms of requests to the agency) related to the Agency's statutory obligations?

The Agency has established a docket to receive any ideas you may wish to propose. Comments may be submitted in writing to Docket No. 98N-0339 at the following address: Dockets Management Branch, Food and Drug Administration, Room 1061, HFA-305, 5600 Fishers Lane, Rockville, MD 20857.

This public meeting is free of charge; however, registration is required and due to space limitations, early registration is recommended. If you wish to attend either of the meetings, please submit your name and affiliation via facsimile to the following individuals: (1) for the August 14th meeting in Washington, contact Gail Sherman, phone 301-827-1315, FAX 301-827-3079, e-mail sherman@cber.fda.gov; and (2) for the August 28th meeting in Oakland, CA, contact Mark Roh, phone 510-637-3980, FAX 510-637-3977, e-mail mroh@ora.fda.gov. If you would like to make a presentation, please send your name, title, affiliation, street address, e-mail address and telephone and fax numbers, along with a short description of the topic you wish to address, to the appropriate contact person listed above. The deadline for receiving requests to speak is Friday, July 31, 1998. Each person who submits a request will receive a response by August 5 stating whether they have been included in the program.

I look forward to hearing your views and suggestions as we are committed to carrying out these consultations in a spirit of candor and cooperation. If you have any questions, please contact Dennis Strickland at 301-827-2000.

Sincerely,

Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation
and Research

Enclosure